

HFA-305, Section 174,  
Docket

Date of Approval:

DEC 31 2001

## **FREEDOM OF INFORMATION SUMMARY**

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

**NADA 111-636**

**LINCOMIX® Soluble Powder  
(lincomycin hydrochloride)**

“For Revision of the Approved LINCOMIX Soluble Powder Insert Labeling Replacing a Caution for Use Only in Swine Weighing Less than 250 Pounds with a Caution Indicating Safety Has Not Been Demonstrated for Pregnant Swine or Swine Intended for Breeding.”

**SPONSORED BY:**

**PHARMACIA & UPJOHN**

FOIS-1

**I. GENERAL INFORMATION**

NADA Number: 111-636

Sponsor: Pharmacia & Upjohn  
7000 Portage Road  
Kalamazoo, Michigan 49001

Established Name: Lincomycin Hydrochloride

Proprietary Name: LINCOMIX® Soluble Powder

Marketing Status: OTC

Effect of Supplement: Provides for revision of the approved LINCOMIX Soluble Powder Insert Labeling replacing a caution for use only in swine weighing less than 250 pounds with a caution indicating safety has not been demonstrated for pregnant swine or swine intended for breeding.

**II. INDICATIONS FOR USE**

Swine: For the treatment of swine dysentery (bloody scours).

Broiler chickens: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**III. DOSAGE****A. Dosage Form**

Soluble powder

**B. Route of Administration**

Oral

**C. Recommended Dosage**

Swine: 250 mg of lincomycin per gallon of drinking water

Broiler chickens: 64 mg of lincomycin per gallon of drinking water

**IV. EFFECTIVENESS**

No further effectiveness data were required.

**V. ANIMAL SAFETY**

The 250-pound weight restriction has been removed due to swine feeding practices today resulting in heavier weights being reached in pigs before slaughter. The statement "The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding." has been added to the label to caution against use in these animals.

**VI. HUMAN SAFETY**

No further human food safety data were required.

**VII. AGENCY CONCLUSIONS**

The information submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) for LINCOMIX® Soluble Powder for Swine, allows for the removal of the 250 lb weight restriction.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

**VIII. APPROVED PRODUCT LABELING**

LINCOMIX® Soluble Powder facsimile label.

Copies of applicable labeling may be obtained by writing to:

Freedom of Information Staff (HFI-35)  
Food and Drug Administration, Room 12A16  
5600 Fishers Lane  
Rockville, Maryland 20857

NDC 0009-0962-18

# LINCOMIX<sup>®</sup>

Soluble Powder

lincomycin hydrochloride  
(agricultural grade)  
soluble powder  
Antibacterial



FOR ORAL USE IN SWINE AND  
BROILER CHICKENS ONLY

Each packet contains as active ingredient:  
Lincomycin hydrochloride,  
equivalent to lincomycin ..... 32 grams

NADA #111-636; Approved by FDA

Pharmacia  
& Upjohn

NET CONTENTS  
24-80 g (2.82 Oz) PACKETS

Restricted Drug—Use Only as Directed (California)

#### SWINE: Directions for Use

**INDICATION:** LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** Each packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

#### BROILER CHICKENS: Directions for Use

**INDICATION:** LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water. **TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** Each packet will medicate 500 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

#### CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer or breeder chickens.

#### WARNINGS

1. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
2. Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].

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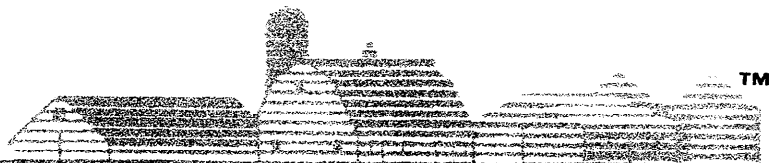
NDC 0009-0962-18

# LINCOMIX®

Soluble Powder

**lincomycin hydrochloride  
(agricultural grade) soluble powder**

**Antibacterial**



**FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY**

The packet contains as active ingredient:  
Lincomycin hydrochloride  
equivalent to lincomycin

82 grams

NADA 141-636 Approved by FDA



**Pharmacia  
& Upjohn**

**NET WT. 2.82 OZ.  
(80 GRAMS)**

## Restricted Drug—Use Only as Directed (California)

### SWINE: Directions for Use

**INDICATION:** LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** This packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

### BROILER CHICKENS: Directions for Use

**INDICATION:** LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

**TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** This packet will medicate 500 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

### CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer or breeder chickens.

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